PACKAGE LEAFLET: INFORMATION FOR THE USER

ANATERA™ 100 mg/ml solution for injection Fluorescein

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.

Keep this leaflet.

You may need to read it again. If you have any further questions, please ask your doctor. If you get any side effects, talk to your doctor. This includes any possible side effects

not listed in this leaflet.

See section 4.

What is in this leaflet:

- What ANATERA™
 100 mg/ml solution for injection is and what it is used for
- What you need to know before you are given ANATERA™ 100 mg/ml solution for injection
- How ANATERA™
 100 mg/ml solution for injection is given

4. Possible side effects the blood vessels at the back of your eye visible 5. How to store during an eye examination ΔΝΔΤΕΚΑΤΜ (this procedure is 100 mg/ml solution for known as fluorescein injection angiography). This medicine is for diagnostic 6. Contents of the pack use only. It is not used and other information to treat any condition. 7. Information for

the Health care professional

1. What
ANATERA™
100 mg/ml
solution for injection is and what it is used for

ANATERA™ 100 mg/ml

solution for injection is a dye solution that makes injection
You should <u>NOT</u> be given
ANATERA™ 100 mg/ml
solution for injection

2. What you need

you are given

ANATER ATM

solution for

100 mg/ml

to know before

- if you are allergic (hypersensitive)to fluorescein or any other ingredients of this medicine (listed in section 6).
- Tell your doctor if you think you are allergic or hypersensitive to fluorescein or any other ingredients in ANATERATM 100 mg/ml solution for injection.

Warnings and precautions

Tell your doctor before you are given ANATERA™ 100 mg/ml solution for injection:

if you have pre-existing conditions such as cardiovascular disease or diabetes mellitus. if you have impaired kidney function.
Fluorescein angiography testing may weaken or damage kidney function which can be a risk for someone with severe renal disease.
Please consult with your doctor to see if this

necessary, your doctor will give a lower dose of ANATERA™ 100 mg/ml solution for injection. • if you use medicines

test is safe for you. If

if you use medicines called beta blockers.
Beta blockers are used to treat high blood pressure and a number of heart conditions and are also used in eye drops for the treatment of glaucoma. An

to ANATERA™ 100 mg/ml solution for injection can cause a sudden drop in blood

allergic reaction

pressure. This may be greater in patients taking beta blockers (such as atenolol, sotalol, propranolol, metoprolol, bisoprolol).

if you have had a reaction to fluorescein before. You may need to be given another drug to prevent you feeling sick

if you are on a low sodium diet.

ANATERA™ 100 mg/ ml solution for injection

If any of the above applies to you, or if you are not

contains up to 3.15

mmol (72.45 mg)

sodium per dose.

sure, please tell your doctor before you are given ANATERA™ 100 mg/ ml solution for injection.

Other medicines and ANATERA™ 100 mg/ ml solution for injection.

Tell your doctor if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. This medicinal product must not be mixed with

other medicinal products.

Pregnancy, breastfeeding and fertility

Pregnancy and fertility

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

If you are pregnant,
ANATERA™ 100 mg/
ml solution for injection
should only be used
after your doctor has
prescribed it. Due to
limited experience,
caution should be
exercised when
considering the use of
ANATERA™ 100 mg/
ml solution for injection
during pregnancy.

Breast feeding

Tell your doctor if you

are breast feeding. Fluorescein, the active substance in ANATERA™ 100 mg/ml solution for injection, passes into the mother's milk where it is slowly eliminated. Therefore, after using ANATERA™ 100 mg/ ml solution for injection, you should not breast feed for 7 days. During this period, breast milk should be expressed and thrown away.

Driving and using machines

As part of your eye examination, you may be given eye drops which increase the size of the

pupil of your eye. This can temporarily affect your vision and your ability to drive or use machines. Do not drive or use machinery until your vision has returned to normal.

Important information about some of the ingredients of ANATERA™ 100 mg/ml solution for injection

This medicinal product contains 72.45 mg sodium (main component of cooking/table salt) in each 5ml. This is equivalent to 3.7% of the recommended maximum daily dietary intake of sodium for an adult.

3. How
ANATERA™ 100
mg/ml solution
for injection is
given

ANATERA™ 100 mg/ml solution for injection will be administered by your doctor. Depending on your condition your doctor may modify the dose. However, since this product has not been studied in children, dose-adaptation data for children are not available. Therefore, ANATERA™ 100 mg/ml solution for injection should not be used in patients below 18 years as efficacy and

safety in this group have not been established.

By injection: Like all medicines, ANATERA™ 100 mg/ Usually one vial of ml solution for injection ANATERA™ 100 ma/ can cause side effects. ml solution for injection although not everybody is given by injection gets them. The following into a vein in the arm. side effects have been ANATERA™ 100 mg/ reported: ml solution for injection should not be injected Very common side effects intrathecally (into the May affect more than spinal canal) or intra-1 in 10 people arterially (into the arteries). Nausea If you have any further Common side effects questions about how ANATERA™ 100 ma/ml May affect up to solution for injection is 1 in 10 people given, ask your doctor.

4. Possible side effects

 problems, fainting, itching, escape of blood or fluid into the tissue.

Vomiting, stomach

Uncommon side effects	Very rare side effects
May affect up to 1 in 100 people	May affect up to 1 in 10,000 people
Headache, dizziness, sensation of pins and needles, cough, throat tightness, abdominal pain, hives, impaired speech, pain, feeling hot, hypersensitivity, inflammation of the veins Rare side effects May affect up to 1 in 1,000 people Severe allergic reaction, cardiac arrest, low blood pressure, shock, difficulty	Anaphylactic shock, convulsion, angina pectoris, slow heart rate, fast heart rate, high blood pressure, cramp of blood vessels, cramp in the calf muscles, poor circulation, skin flushing, pallor, hot flush, stopping breathing, fluid on the lungs, asthma, decreased breathing function, swelling of the larynx, shortness of breath, swelling of the nose, sneezing.
in breathing or wheezing (bronchospasm)	Not known (frequency cannot be estimated from the available data) Stroke, chest pain, loss of
8	

consciousness, shaking, abnormal or decreased skin sensation, rash, cold sweat, skin inflammation, sweating, oedema, generalised weakness, myocardial infarction,

throat irritation, skin

discolouration, abnormal

sense of taste and chills.

After receiving

ANATERA™ 100 mg/
ml solution for injection,
you may experience a
change in the way things
taste. Your skin may
appear yellowish; this
discoloration usually
disappears after 6-12
hours. Your urine also

may appear bright yellow;

this may take 24-36 hours to return to normal.

After injection, inflammation of the vein and blood clots in the vein may occur. If during injection the solution leaks from the vein into the surrounding tissues. it can cause damage to the skin and inflammation of the veins, nerves and tissues close to the injection site; this can lead to severe pain. If you notice any pain or other problems at the injection site, tell your doctor; you may need to be given pain medication or other treatment to help with

As listed previously, fluorescein can have unexpectedly severe side effects.

this.

These are more likely if you have suffered a reaction to fluorescein before or if you suffer from allergies (food or drug allergies), eczema, asthma or hay fever.

If you experience any of the side effects, or if you notice any side effects not listed in this leaflet, please tell your doctor.

Blood and urine tests
It is possible that
fluorescein may affect
certain blood and urine
tests for 3 to 4 days after
you are given it. If you
have any blood or urine
tests or further X-rays
during this period, tell
your doctor that you have

been given fluorescein.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom Yellow Card Scheme

Website: www.mhra.gov. uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

5. How to store ANATERA™ 100 mg/ml solution for injection

Keep this medicine out of the sight and reach of children

- Do not use this medicine after the expiry date which is stated on the label and outer carton (marked 'Exp'). The expiry date refers to the last day of that month.
- Once opened the vial must be used immediately.
- Your doctor or nurse knows how to store ANATERA™ 100 mg/ml solution for injection:
- Do not store above 25°C.
 Do not freeze.

Keep the vial in the outer carton in order to protect from light.

- Do not use ANATERATM 100 mg/ml solution for injection if the vial is cracked or damaged in any way.
- The solution is to be inspected visually for particulate matter and discoloration prior to administration. The solution should only be used if the solution is clear and free from particles

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use.

These measures will help protect the environment.

6. Contents of the pack and other information

What ANATERA™ 100 mg/ ml solution for injection contains

The active substance is fluorescein.

1 ml of solution contains 100 mg fluorescein (as 113.2 mg fluorescein

sodium).

One vial with 5 ml contains 500 mg fluorescein (as 566 mg fluorescein sodium). The other ingredients are sodium hydroxide and / or hydrochloric acid (used to adjust the pH of the solution) and water for injections.

What ANATERA™ 100 mg/ ml solution for injection looks like and contents of the pack

ANATERA™ 100 mg/ml solution for injection is a clear red-orange solution for injection.

ANATERA™ 100 mg/ ml solution for injection is available in packages containing 12 vials of 5 ml solution for injection. Marketing Authorisation Holder Alcon Eye Care UK Limited Park View, Riverside Way Watchmoor Park, Camberley

Surrey, GU15 3YL United Kingdom PL 41809/0001

This product is also authorised in the EU under the following names:

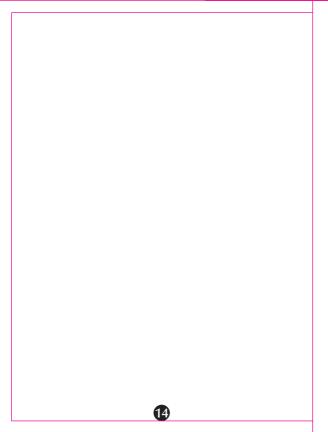
Fluorescein ALCONTM
10% and FLUORESCITETM
100 mg/ml solution for
injection

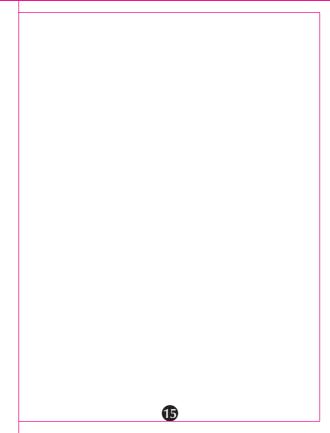
Manufacturer: Alcon Laboratories Belgium Lichterveld 3 2870 Puurs-Sint-Amands Belgium This leaflet was last revised in 05/2021

7. Information for Health care professionals

The complete SmPC is provided as a separate document in the medicinal pack.

© 2021 Alcon Inc.





A1694074-0521